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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/005,646 | 12/07/2001 | Peter W. Bringmann | BERLX 87 | 7678 |

23599 7590 09/30/2003

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EXAMINER

SAOUD, CHRISTINE J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/005,646 | BRINGMANN ET AL. | |
| | Examiner | Art Unit | |
| | Christine J. Saoud | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a method of treating spinal cord damage or trauma by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- II. Claims 1-6, drawn to a method of treating neuronal tissue damage by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- III. Claims 1-6, drawn to a method of treating Huntington's disease by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- IV. Claims 1-6 and 34, drawn to a method of treating multiple sclerosis by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- V. Claims 1-6, drawn to a method of treating myelopathy by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- VI. Claims 1-6, drawn to a method of treating myelitis by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.

- VII. Claims 1-6, drawn to a method of treating syringomyelia by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- VIII. Claims 7-11, drawn to a method of treating spinal cord damage or trauma by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- IX. Claims 7-11, drawn to a method of treating neuronal tissue damage by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- X. Claims 7-11, drawn to a method of treating Huntington's disease by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XI. Claims 7-11 and 35, drawn to a method of treating multiple sclerosis by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XII. Claims 7-11, drawn to a method of treating myelopathy by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XIII. Claims 7-11, drawn to a method of treating myelitis by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.

- XIV. Claims 7-11, drawn to a method of treating syringomyelia by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XV. Claims 36-41, drawn to a method of treating spinal cord damage or trauma by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XVI. Claims 36-41, drawn to a method of treating neuronal tissue damage by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XVII. Claims 36-41, drawn to a method of treating Huntington's disease by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XVIII. Claims 36-41 and 69, drawn to a method of treating multiple sclerosis by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XIX. Claims 36-41, drawn to a method of treating myelopathy by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XX. Claims 36-41, drawn to a method of treating myelitis by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.

- XXI. Claims 36-41, drawn to a method of treating syringomyelia by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XXII. Claims 42-46, drawn to a method of treating spinal cord damage or trauma by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- XXIII. Claims 42-46, drawn to a method of treating neuronal tissue damage by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- XXIV. Claims 42-46, drawn to a method of treating Huntington's disease by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- XXV. Claims 42-46 and 70, drawn to a method of treating multiple sclerosis by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- XXVI. Claims 42-46, drawn to a method of treating myelopathy by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- XXVII. Claims 42-46, drawn to a method of treating myelitis by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.

- XXVIII. Claims 42-46, drawn to a method of treating syringomyelia by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- XXIX. Claims 12-17, drawn to a method of treating adrenal leukodystrophy by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- XXX. Claims 12-17, drawn to a method of treating progressive multifocal leukoencephalopathy by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- XXXI. Claims 12-17, drawn to a method of treating encephalomyelitis by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- XXXII. Claims 12-17, drawn to a method of treating Guillian-Barre syndrome by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- XXXIII. Claims 12-17, drawn to a method of treating paraproteinemia by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- XXXIV. Claims 12-17, drawn to a method of treating chronic inflammatory demyelinating polyneuropathy by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.

- XXXV. Claims 18-22, drawn to a method of treating adrenal leukodystrophy by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XXXVI. Claims 18-22, drawn to a method of treating progressive multifocal leukoencephalopathy by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XXXVII. Claims 18-22, drawn to a method of treating encephalomyelitis by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XXXVIII. Claims 18-22, drawn to a method of treating Guillian-Barre syndrome by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XXXIX. Claims 18-22, drawn to a method of treating paraproteinemia by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XL. Claims 18-22, drawn to a method of treating chronic inflammatory demyelinating polyneuropathy by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- XLI. Claims 47-52, drawn to a method of treating adrenal leukodystrophy by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.

- XLII. Claims 47-52, drawn to a method of treating progressive multifocal leukoencephalopathy by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XLIII. Claims 47-52, drawn to a method of treating encephalomyelitis by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XLIV. Claims 47-52, drawn to a method of treating Guillian-Barre syndrome by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XLV. Claims 47-52, drawn to a method of treating paraproteinemia by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XLVI. Claims 47-52, drawn to a method of treating chronic inflammatory demyelinating polyneuropathy by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.
- XLVII. Claims 53-57, drawn to a method of treating adrenal leukodystrophy by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- XLVIII. Claims 53-57, drawn to a method of treating progressive multifocal leukoencephalopathy by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.

- XLIX. Claims 53-57, drawn to a method of treating encephalomyelitis by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- L. Claims 53-57, drawn to a method of treating Guillian-Barre syndrome by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- LI. Claims 53-57, drawn to a method of treating paraproteinemia by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- LII. Claims 53-57, drawn to a method of treating chronic inflammatory demyelinating polyneuropathy by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.
- LIII. Claims 23-28, drawn to a method of promoting graft survival by administration of an FGF-20 polypeptide, classified in class 530, subclass 399, for example.
- LIV. Claims 29-33, drawn to a method of promoting graft survival by administration of an FGF-20 nucleic acid, classified in class 514, subclass 44, for example.
- LV. Claims 58-63, drawn to a method of promoting graft survival by administration of an FGF-9 polypeptide, classified in class 530, subclass 399, for example.

LVI. Claims 64-68, drawn to a method of promoting graft survival by administration of an FGF-9 nucleic acid, classified in class 514, subclass 44, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-LVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to 56 different methods which have distinct goals (modes of operation, different functions and effects), patient populations, method steps and starting materials.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 703-305-7519. The examiner can normally be reached on Monday through Thursday 8:00AM-2:00PM; voice mail service is available.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud